Robert A. Paarlberg, Senior Director
Global *Regulatory Affairs*
Mailstop 0636-298-112

TELEPHONE (616) 833-0646
Facsimile No. (616) 833-8237

01368 98N-0583 C17 00006

July 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Re: Docket 98N-0583

Exports: Notification and Recordkeeping Requirements; Proposed Rule (FR Notice April 2, 1999)

Dear Sir or Madam:

Pharmacia & Upjohn is a U.S.-based research and manufacturing corporation who markets and distributes drugs, devices and biologics throughout the world. The FDA Export Reform and Enhancement Act of 1996 (Export Act) opened substantive new opportunities for global research and development of new drugs, animal drugs, biological products and medical devices. Most all barriers to using the U.S. as the sourcing point for clinical trial and finished new drugs, which are in full compliance with foreign requirements, have been removed.

It should be kept in mind, however, that Congress adopted the 1996 Export Act in large part because of the Agency's overly restrictive interpretation of the provisions of the 1986 Export Act. The manner in which the Agency implemented that law effectively denied U.S.-based manufacturers the benefits intended by Congress when it adopted the 1986 Export Act. As a consequence, many companies moved some of their operations overseas in order to globally distribute products in an efficient manner.

The burdensome new administrative reporting requirements in the proposed rule and the potential delays in obtaining the necessary documentation from foreign governments will make it more difficult for U.S.- based companies to conduct clinical trials outside the U.S. The proposed rule as written will also impede the export of products from the Unites States.

Pharmacia & Upjohn supports PhRMA's comments on the proposed rule for "Exports: Notification and Recordkeeping Requirements". We believe that the FDA has incorporated

98N-0583 C17

requirements that are beyond the intent and language of the statute and appears to be repeating the mistakes of the past. Not only do these provisions exceed the congressional intent, they consume valuable FDA resources that can be more appropriately directed.

We feel that the 1996 Export Act provides a sufficient framework for the export of products that is essentially self-executing and therefore, the Agency should withdraw the proposed rule and bring FDA's implementation in line with the letter and spirit of the 1996 Export Act.

Pharmacia & Upjohn offers the following comments on the draft guidance:

21 CFR §1.101(b) Notification and Recordkeeping

Proposed 1.101(b) (2) which requires companies obtain a letter, or other documentary proof, from a foreign government or agency stating that the product has marketing approval from the foreign government or does not conflict with that country's laws, is outside the scope of FDA's authority. Many foreign governments do not have resources to issue such letters, and consequently, would constitute a significant burden on the foreign government and substantial delays would be anticipated. Congress did not intend that the 1996 Export Act would make such a provision. Such a requirement would impose an unwarranted additional administrative burden to the exportation of drugs and would in practice defeat the intent of the 1996 Export Act. Certification by a company that the drug is approved for marketing and does not conflict with the laws of the importing country should be adequate and is consistent with the intent of the statute.

In addition, obtaining such a letter would also significantly impact the initiation of clinical studies conducted outside the United States if clinical trial supplies would be exported from the United States.

Notification under 1.101(d) providing a listing of all the countries which receive an exported product creates additional reporting requirements which are beyond the "simple notification" intended by Congress when a drug is "first" exported.

The 1996 Export Act also allows a company to export an unapproved drug to any listed country in order to fill the pipeline. Products exported under Section 802(d) require no notification or reporting requirements. Yet the proposed rule requires that companies notify FDA when they export products under this section.

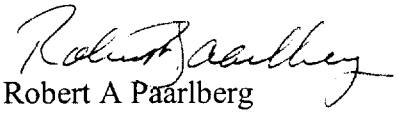
Complying with 1.101(b)(2), will take additional personnel. We estimate that we will need 2.5 FTEs annually to comply with the proposed rule. In addition, we estimate that we will also need to spend $50,000 - $100,000 in capital costs to upgrade computer systems in order to comply with the requirements of the proposed rule.

The draft guidance does not take into account another fact. Namely, that once clinical trial materials are imported into a listed country, they are from that point forward the subject of regulation by the local competent authorities. Any decision as to whether clinical materials imported from the U.S. should be allowed subsequent shipment to another country is made pursuant to the local laws and regulations governing such exports. It is a matter solely within the discretion of the listed country authorities whose competence Congress has specifically acknowledged. Again, the draft guidance in its fundamental effect would defeat the intent of Congress and deny the right of the local competent regulatory authorities to make that determination.

We appreciate this opportunity to provide comments and look forward to working with the Agency to ensure that the 1996 Export Act is implemented in a manner consistent with the intent of Congress.

Sincerely,

Pharmacia & Upjohn



Robert A Paarlberg
Senior Director, Global Regulatory Affairs

exprec1.doc

here

FOR SHIPMENTS WITHIN U.S. ONLY

PLEASE TYPE OR PRINT

FROM

Robert A. Paarlberg

TO

Food & Drug Administration

12420 Parklawn Drive, Room 1-23

Rockville MD 20857

DOCKETS Management Branch(HFA-305

Preprint Format No.

Origin

Airbill Number 803966426

Method of Payment

Assumed sender unless otherwise noted

- Bill Sender
- Bill Receiver
- Bill 3rd Party
- Paid in Advance

AIRBORNE EXPRESS.

EXP (Letter - 150 lbs)

NAS (Letter - 5 lbs)

SDS (Letter - 150 lbs)

Billing Reference will appear on invoice

NO. of Pkgs.	Weight (LBS)	One box must be checked: Letter Express	Express Pack	Other Packaging
1	1	X		

Special Instructions

- SAT
- HAA
- LAB

* 8 0 3 3 9 6 6 4 2 6 *

001 (9/98) S-06
PACKAGE LABEL

MLDA4X

Remember: Airborne Express cannot deliver without your airbill attached here.